

UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

JONATHAN A. BLOOM,)	
)	
Plaintiff,)	
)	
v.)	Civil Action No. 5:16-cv-121
)	
SYLVIA BURWELL in her official capacity)	
as Secretary, United States Department)	
of Health and Human Services,)	
)	
Defendant.)	

PLAINTIFF'S POST-HEARING MEMORANDUM

Plaintiff, Jonathan A. Bloom, by his undersigned counsel, files this Post-Hearing Memorandum in response to issues raised during the hearing.

Dr. Bloom believes that a remand is unnecessary because the documents that may not be in the administrative record and which support his claim that CGM is not precautionary for Type 1 Diabetes are public documents of which this Court can take judicial notice; the Secretary has not met the legal requirements for remand; and the Secretary seeks a remand solely to amend her basis of denial. Yet, Dr. Bloom acknowledges that the Medicare Appeals Council ("MAC") apparently took judicial notice of at least one document and put it in the administrative record, i.e., a print-out of the Medtronic website, without giving Dr. Bloom an opportunity to address any issues raised by that document. Accordingly, a remand may provide Dr. Bloom an opportunity to respond to that issue and put directly in the administrative record various documents in the public domain that support his position that CGM is not precautionary.

A. The Secretary Should Produce the Administrative Record to Plaintiff Immediately.

Rather than answering the complaint or producing the administrative record to enable the parties to develop the case, the Secretary sought an extension to produce the administrative record. *See* Doc. 6. Nonetheless, as of September 29, 2016, the MAC had not prepared the administrative record for one of the cases despite representing that Medicare beneficiary appeals are given “top priority.” In view of the Secretary’s statements regarding the contents of the administrative record, which the Secretary declined to produce despite requesting an extension to enable complete production, and in further view of the MAC’s improper addition to the administrative record without affording a Medicare beneficiary the opportunity to address, the Secretary should produce the administrative record in both cases to Dr. Boom. Such production will enable Dr. Bloom to better prepare his case on remand and will ensure expeditious production of the administrative record if further proceedings before this Court are necessary.

B. The MAC Should Be Directed to Decide and/or Remand the Cases Expeditiously.

The delays in resolution of this case are in breach of BIPA, which provides that when resolving Medicare appeals for denied claims, the MAC should issue decisions within 90 days of an appeal or Own Motion Review. *See* 42 C.F.R. §405.1100. In the present case, the MAC took at least 261 days to issue M-15-4332. Despite prior District Court rulings instructing the MAC not to accord deference to Article 33614, the Secretary has advocated for a remand based on the MAC’s apparent “error of law” in deferring to Article 33614. Further, the MAC issued yet another decision on the issue in August 2016 indicating that the MAC will continue to rely on Article 33614 when issuing decisions relating to CGM. *See J.B.*, M-15-907 (Aug. 8, 2016).

The MAC is empowered to take all actions that an ALJ can take to develop the administrative record. *See* 42 C.F.R. §405.1108(d)(2). Under 42 C.F.R. §405.1138, when a case

is remanded by a District Court, the MAC may either issue a decision or remand the matter back to the ALJ level. Historically, the MAC has remanded matters back to the ALJ level to allow full development of the case. However, in view of the MAC's recent decision on substantially the same issue, and in further view of the already statutory-breaching delay the MAC has caused in rendering the decisions currently pending before the Court, Dr. Bloom requests that the Court order the MAC to (1) produce the administrative record to Dr. Bloom; (2) afford Dr. Bloom the opportunity to submit additional evidence to the administrative record to address issues raised by the MAC's decision, including testimony, at the MAC; and (3) issue a decision within 30 days of the Court's remand order.

Alternatively, the Court may grant the Secretary discretion on whether the MAC should remand the matter back to the ALJ level provided the ALJs are instructed to issue timely decisions. The failure of ALJs to meet the statutory timelines in rendering decisions has been the subject of at least one class action lawsuit. *See Exley v. Burwell*, 3:14-cv-0120 (D. Conn. Sept. 1, 2016). In an effort to resolve that case, the Secretary represented that ALJs currently are resolving cases within 56.5 days. *See Ex. 1 (Exley, 3:14-cv-0120 Doc. 80-3, Ex. 1, Att. 1)*. In an effort to ensure the most expeditious resolution of the lengthy Medicare appeals process, this case may be returned to each of the three ALJs who previously were assigned this matter. Each of the ALJs will already be familiar with the existing administrative record. Based on that familiarity, Dr. Bloom believes the ALJs will be able to render a more expeditious decision than a single ALJ who would be required to consider an administrative record and decision compiled by a different judge. If an ALJ decision is unfavorable and is appealed by Dr. Bloom to the MAC, or the MAC decides to exercise Own Motion Review on a favorable ALJ decision, the MAC should be compelled to issue a decision within 30 days of either the filing of an appeal of

an unfavorable ALJ decision or within 30 days of the MAC's review of a favorable ALJ decision.

Dr. Bloom believes either of the foregoing proposals will enable full development of the administrative record and also enable timely resolution of a matter that has been pending within the agency for an extended time. Dr. Bloom has Type 1 diabetes with hypoglycemic unawareness. Although diabetes afflicts thousands of Medicare beneficiaries, most of those individuals have Type 2 diabetes. Individuals who were diagnosed with Type 1 diabetes between the years 1950 and 1964 had a life expectancy of 53.4 years. *See* Miller et al., "Improvement in Life Expectancy of Type 1 Diabetes," *Diabetes*, Nov. 2012: 61(11):2987-2992. Thus, most of Dr. Bloom's contemporaries who had Type 1 diabetes did not reach Medicare age. Dr. Bloom can ill-afford endless administrative delays for resolution of whether Medicare should cover the continuous glucose monitor, which is nationally and internationally recognized as the standard of care and which will enable him to avoid life-endangering hypoglycemic events.

Based on the foregoing, Dr. Bloom respectfully requests, if the Court elects to remand this matter, that the Court's Order contain the language in the proposed Order attached as Exhibit 2.

Dated at Burlington, Vermont this 5th day of October, 2016.

Respectfully submitted,

JONATHAN A. BLOOM

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CERTIFICATE OF SERVICE

I, Craig S. Nolan, counsel for Jonathan A. Bloom, do hereby certify that on October 5, 2016, I electronically filed with the Clerk of Court the following document:

PLAINTIFF'S POST-HEARING MEMORANDUM AND PROPOSED ORDER

using the CM/ECF system. The CM/ECF system will provide service of such filing via Notice of Electronic Filing (NEF) to the following NEF parties:

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Dated at Burlington, Vermont this 5th day of October, 2016.

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